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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,175	06/26/2003	Peter David White	1145-222	5191
23524	7590	10/16/2006	EXAMINER	
FOLEY & LARDNER LLP 150 EAST GILMAN STREET P.O. BOX 1497 MADISON, WI 53701-1497			ANDERSON, JAMES D	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,175	WHITE ET AL.	
	Examiner James D. Anderson	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 September 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 is/are rejected.
- 7) Claim(s) 1-7 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1 sheet</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-7 in the reply filed on 9/22/2006 is acknowledged. Applicant's further election, without traverse, of Compound 3, wherein X = OH, as shown in Figure 4 is acknowledged. The elected compound has been determined to be free of the prior art. The search has been expanded to include other species from the claimed genus. The Election of Species requirement is hereby withdrawn.

Claims 8-9 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/22/2006.

Status of the Claims

Claims 1-9 are pending and are the subject of this Office Action. Claims 8-9 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-7 are under examination. This is the first Office Action on the merits of the application.

Claim Objections

Claims 1-7 are objected to because of the following informalities: it appears an "A" is missing from the beginning of the claims (*i.e.* "A building block..."). Appropriate correction is required.

Claim Rejections - 35 USC § 112 – First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case, the claims recite structural limitations defined only by intended purpose. For example, claim 1 recites functionalities for: A) attaching to a solid support; B) attaching one or more amino acids or peptides; and C) attaching one or more labels. There is insufficient written description in the specification for the following broad functionalities recited in formula I:

- 1) Functionality for the attachment to a solid support or a functionality already comprising a solid support
- 2) Functionality for the attachment of one or more amino acids or peptides or a functionality already comprising one or more amino acids or peptides
- 3) Functionality for the attachment of one or more labels or a functionality already comprising one or more labels

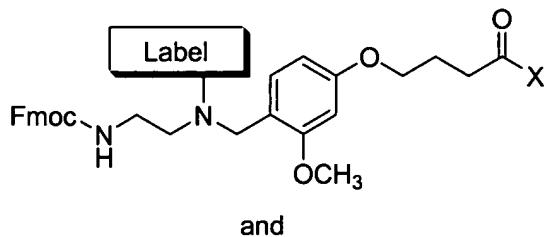
In addition, there is insufficient written description for the term “label” in the specification.

M.P.E.P. § 2163 states, “An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by ‘whatever characteristics sufficiently distinguish it’. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.”

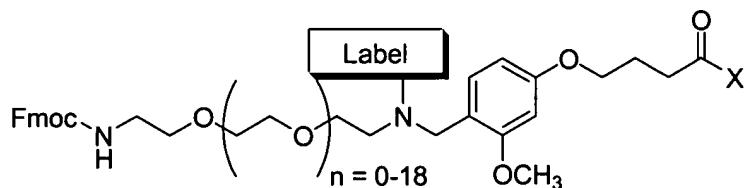
With regard to the term “label”, there is no description in the specification of *structural characteristics* that define a residue or compound as a label. “Labels” are defined on page 6, lines 19-31 of the specification, which also refers to a book for “further information” but no examples are provided *except* those shown in the compounds found in Figure 4.

The specification defines “functionality” as any “residue, especially a chemical residue which has a given, defined function” (page 7, lines 18-19). Applicants state, in multiple instances, that suitable residues and reaction conditions are known to those skilled in the art and refer to journal articles and books for examples (*e.g.* page 9, lines 3-5). However, the incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The instant disclosure only describes two genuses of building blocks with similar structures (*i.e.* the core structure of the compounds shown in Figure 4):



and



Only one structural example of “*a functionality* for the attachment to a solid support” is described in the specification (page 9, lines 18-27). Similarly, only two preferred residues are described for “*a functionality* for the attachment of one or more amino acids or peptides” (page 10, lines 17-22). Finally, “*a functionality* for the attachment of one or more labels” is not structurally defined in the specification. It is only stated that it may contain one or more “labels.” The chemical structure of said labels is not defined or described in the disclosure, other than in the compounds shown in Figure 4.

Thus, while the specification describes nine specific building blocks (Figure 4), including the elected species, it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by formulas (I) and (II). There is only adequate written description for the core structures shown above, further exemplified in the compounds shown in Figure 4.

Claim Rejections - 35 USC § 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites a residue according to formula II. In said formula, it is not clear what other substituents are present on the carbon attached to “Z”. It appears this carbon only has three bonds.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

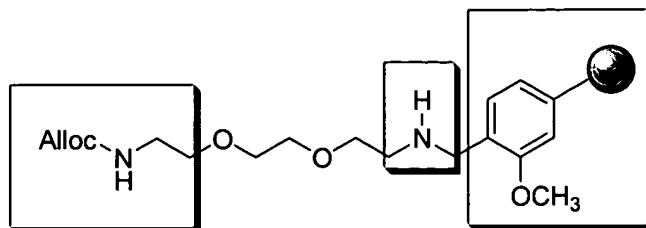
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

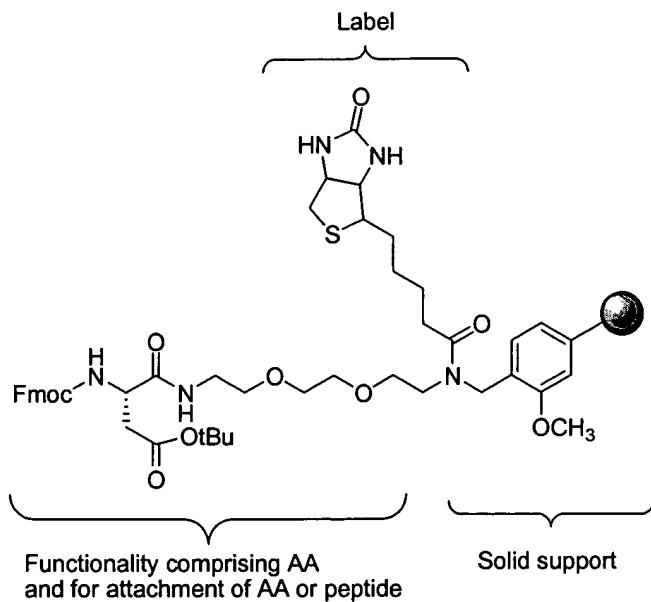
Claims 1-6 are rejected under 35 U.S.C. § 102(a) as being anticipated by Kumar *et al.* (prior art of record).

Kumar *et al.* teach a solid phase strategy for synthesizing labeled peptides (Abstract).

The building block of this strategy comprises a functionality attached to a solid support, functionality for attaching one or more amino acids or peptides, and a functionality comprising a label (Scheme 1). For example, the following “building block” is exemplified in the reference:



The “Alloc” protected amine corresponds to applicant’s claimed “B” functionality that is for the attachment of one or more amino acids or peptides. The “NH” group corresponds to applicant’s claimed “C” functionality that is for the attachment of a label. Finally, the substituted aryl corresponds to applicant’s claimed “A” functionality that is for the attachment to a solid support or *already comprising* a solid support. Attachment of an amino acid and label to the building block are demonstrated in Scheme 1 of the reference:



The reference thus teaches all of the limitations of the instant claims, namely a building block with functionalities for attachment to solid support, for attachment to one or more amino acids or peptides, and for attachment of one or more labels.

Claims 1-2, 4 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by

Fehrentz *et al.* (Tetrahedron Letters, 1995, vol. 43, pages 7871-7874).

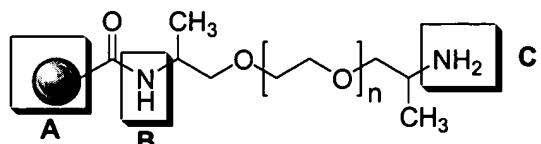
Fehrentz *et al.* teach a building block for the synthesis of peptides with the following structure:



Clearly this “building block” anticipates the instant claims as it comprises functionalities for the attachment of a label, for the attachment of amino acids and is attached to a solid support.

Claims 1, 4 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Meldal *et al.* (Tetrahedron Letters, 1992, vol. 21, pages 3077-3080) in view of “PL-PEGA Resin” Product Information Sheet (printed from www.polymerlabs.com on 10/4/2006).

Meldal *et al.* teach polyethylene glycol dimethyl acrylamide copolymers for use in solid phase synthesis (Abstract). The copolymers can be attached to resins (page 3079). It is noted that these “PEGA” resins are commercially available (please see “PL-PEGA Resin” information page, copy attached). The PL-PEGA resin has the following structure:



Note that the resin has functionalities for attachment of amino acids (C) and labels (B) and is attached to a solid support (A) as required by the limitations of the instant claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



James D. Anderson
Patent Examiner
AU 1614

October 3, 2006



ARDIN H. MARSCHEL 10/8/06
SUPERVISORY PATENT EXAMINER